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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

June 28, 2004

Ref: 04-DAL-WL-23

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Louis G. Chagouris, President
Stellar Seafood and Game, LLP
25186 IH 45N. Suite F
Spring, Texas 77386

Dear Mr. Chagouris:

We inspected your firm, Stellar Seafood and Game, LLP, located at 25186 IH 45N, Suite F, Spring, Texas 77386 on April 1, 2, 8, and 13, 2004. Our inspection found that your firm has serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). In accordance with 21 CFR §123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §342(a)(4). Accordingly, your fresh, farm-raised Crawfish, farm-raised Redfish, farm-raised Striped Bass, wild-caught live Blue Crabs, fresh refrigerated cooked crabmeat, vacuum-packaged fresh and frozen Finfish, fresh Tuna, fresh Amberjack, and fresh Mahi-Mahi are all adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

The deviations that were found during the inspection were as follows:

1. Pursuant to 21 CFR §123.6(a), your firm is required to conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and to identify the preventive measures that your firm will apply to control those hazards. Also, pursuant to 21 CFR §123.6(b), your firm must have and

implement a HAACP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur.

Your firm, however, does not have a HACCP plan to control the following food safety hazards that are reasonably likely to occur: pathogen growth in fresh, refrigerated cooked crabmeat; *Clostridium botulinum* in vacuum-packaged fresh and frozen Finfish; chemicals and drugs in farm-raised Crawfish, farm-raised Redfish, farm-raised Striped Bass; and environmental chemicals/pesticides in wild live Blue Crabs.

2. Pursuant to 21 CFR §123.6(c)(2), your firm's HACCP plan must, at a minimum list the critical control points for each of the identified food safety hazards, including as appropriate, critical control points designed to control food safety hazards: (i) that could be introduced in the processing plant environment; and (ii) introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest. A critical control point is defined in 21 CFR §123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." In addition, the HACCP plan must, pursuant to 21 CFR §123.6(c)(3), list the critical limits that must be met at each of the critical control points. "Critical Limit" is defined at 21 CFR §123.3(c) to mean the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

   Your firm's HACCP plan for "GROUP 2 HISTAMINE PRONE FISH (MACKERAL, TUNA, MAHI-MAHI, AMBERJACK)," however, does not list the critical control point of butchering/packaging for controlling the food safety hazard of growth of histamine forming bacteria in scombroid fish. Therefore, the HACCP plan does not have a critical limit of time/temperature, or a monitoring procedure in place to record the cumulative time the histamine-forming fish are exposed to temperatures above 40 degrees Fahrenheit during further processing of these fish.

3. Pursuant to 21 CFR §123.6(c)(7), your firm's HAACP plan must provide for a recordkeeping system that documents the monitoring of the critical control points. Moreover, the records from such monitoring must contain the actual values and observations obtained during monitoring. Your firm, however, did not record monitoring observations at the

receiving and storage critical control points to control histamine forming bacteria listed in your HACCP plan for "GROUP 2 HISTAMINE PRONE FISH (MACKERAL, TUNA, MAHI-MAHI, AMBERJACK)."

We may take further action if you do not promptly correct these violations. For instance, we may initiate regulatory action without further informal notice. Such actions may include the initiation of a seizure action against your products and/or an action to enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as your HACCP plans, copies of all related temperature monitoring records and corrective actions, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Carolyn A. Pinney, Compliance Officer, at the above letterhead address. If you have any questions regarding any issue in the letter, please contact Carolyn A. Pinney at (214) 253-5312.

Sincerely,

Reynaldo R. Rodriguez Jr.
for Michael A. Chappell
Dallas District Director

MAC:cap